

Measuring outcomes with complex patients: an audit of the effect of Actiform Cool on painful wounds

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Abstract

Background: There is growing awareness surrounding the importance of wound pain, recognised by the publication of recent international studies (White, 2008). Wound pain has been identified as an outcome important to patients, in addition to physiological endpoints. It can be difficult to use randomised controlled trials to measure subjective outcomes such as pain, particularly with complex patients. An audit was therefore used to explore the effect of Actiform Cool on wound-related pain. **Methods:** Change in wound-related pain was assessed using a modified Short-Form McGill Pain Questionnaire pre- and post-application of Actiform Cool, and patients were asked to report on any changes in their pain experience, and the effects of this on their activities of daily living. **Results:** Results indicated that 12 patients reported an overall decrease in pain levels following use of the dressing. Four patients reduced their analgesia requirements with one discontinuing opiate analgesics. Five patients reported improvement in their sleep patterns and three reported improved mobility. **Conclusion:** The overall outcome reinforces that Actiform Cool has the potential to reduce pain in some patients when used as part of a pain management plan. **Conflict of interest:** This audit was funded by Activa Healthcare Ltd.

KEY WORDS

Outcome measures
Wound pain
Actiform Cool
Complex wounds

Outcome measurement is a relatively new concept used within healthcare as a means of evaluating the efficacy of various treatments (Price, 1999; Steed et al, 2006). Within the field of wound care, the focus traditionally has been on the measurement of physiologic endpoints, such as speed of healing, percentage change in wound dimensions, changes in exudate levels or rates of infection (Soon and Chen, 2004).

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It is becoming more widely recognised that outcomes that are considered important to health professionals, in terms of the rationalisation of clinical decision making and as part of clinical research, are not necessarily those deemed important by patients. The impact of factors that can influence the health-related quality of life of patients living with a chronic wound, such as changes in mobility and general functioning and control of odour and pain, should be considered as equally important in measuring the success of wound care interventions.

There is a growing awareness among clinicians about the significance of wound pain as an outcome that is important to patients. Pain from chronic wounds can be extremely severe and have a debilitating effect on a patient's physical and mental health. Problems with mobility and disturbed sleep can lead to depression and social isolation (Benbow, 2006; Flanagan, 2006), and previous experience of pain can further exacerbate pain and cause anxiety (Hollinworth, 1997). Several studies have found that patients considered pain to be the worst part of having a leg ulcer, and would often consider pain relief to

be more important than healing (Hyland and Thomson, 1994; Hofman et al, 1997; Husband, 2001).

Understanding of the importance of wound pain in terms of health-related quality of life and its physiological effect on wound healing itself has increased, and so more work on effective methods of minimising wound pain and trauma is being performed. The sheet hydrogel dressing, Actiform Cool (Activa Healthcare, Burton-on-Trent), has been identified as potentially having a pain-relieving effect (Hampton, 2004; Young and Hampton, 2005). In view of the impact that dressings can have on procedural pain and surrounding skin, the research and development of dressings that have the potential to reduce this effect are significant and require further evaluation (Price, 2005).

In terms of outcome measures, measuring the effect of an intervention like the application of a wound dressing, on a so-called 'soft' measure like pain, can be problematic (Greenhalgh, 2001). Difficulties arise when it comes to determining the best methods for measuring these types of outcomes, especially with consideration to the

increasing number and complexity of patients being managed by wound care specialists today. In terms of the established hierarchy of evidence that is widely referred to in the literature (Barton, 2000; Greenhalgh, 2001), randomised controlled trials (RCTs) are considered to be the 'gold standard' method of determining clinical efficacy and providing valid and reliable information regarding the true effect of various interventions (Price, 1999; Greenhalgh, 2001). The issue that presents itself when trying to combine what some would consider proven conventional research methods to measure outcomes with complex patients is that these patients do not necessarily fit into the strict inclusion/exclusion criteria defined by RCTs. These criteria often appear to lead to the requirement for an almost 'perfect' wound or 'perfect' patient that in reality is difficult to find. When this is combined with the evaluation of a complex, personal and subjective experience like wound pain, it is evident that the interpretation of the results of an RCT may not necessarily reflect the true effect of any given intervention as was previously thought. The results of an RCT also do not always readily promote the translation of research into practice and, in the case of patients with complex wounds, do not necessarily always achieve their aim of strictly controlling bias due to a potential lack of external validity.

These issues highlight the need for other approaches to be considered when evaluating new treatments or interventions on patient-centred outcomes for patients with complex wounds, even if these approaches are not deemed to deliver the best evidence in terms of the traditional hierarchy. While case series are often considered to be relatively weak scientific evidence, they can be useful tools for recording interesting cases and exploring subjective experiences from a patient's perspective, while incorporating some more objective measures or tools (Greenhalgh, 2001; Peat et al, 2002). They can also be useful at bridging the gap between theory and practice as they are easy for non-academic clinicians

to understand (Greenhalgh, 2001). As Greenhalgh (2001) stated, evaluating the potential contribution of particular studies to an overall evidence base needs to go beyond placing it into a fixed hierarchy — thus, every study has the potential to provide evidence that can be combined with experience to guide clinical practice, and we should not necessarily only consider changing our practice based on the statistical outcome of certain methods.

In view of this, and with acknowledgement of the complexity of the population of patients routinely seen in clinics, an audit was conducted of the effect of Actiform Cool on wound-related pain, the results of which will be illustrated by descriptions of case studies. The use of an audit with associated case series was considered a more appropriate approach in this case as it provided a more accurate representation of the use of Actiform Cool on patients with the types of painful complex wounds and associated co-morbidities that are often met in the clinical setting. This method also enabled patient views on a personal and subjective experience to be obtained.

Method

The audit sample population was made up of patients attending both complex wound clinics and community leg ulcer clinics over a six-month period. Any patient with a painful wound suitable for treatment with a sheet hydrogel dressing and who was willing to participate was included. Demographic details and medical history and current medications were collected. A full wound assessment was performed using the standardised criteria set out in the normal clinic wound assessment chart. This included assessment of the wound bed, wound edge, surrounding skin, exudate levels and presence of odour. Photographs and area measurements were taken to monitor changes in wound size and appearance as secondary outcome measures.

The primary outcome measure was change in wound-related pain and was assessed using the Short-Form McGill Pain Questionnaire (SF-MPQ) (Melzack, 1987). This assessment tool

was chosen as it is able to capture the nature as well as the intensity of pain experienced. The SF-MPQ is a generic tool that has been shown to be both valid and reliable in several different patient populations (Seymour, 1982; Helme et al, 1989; Dudgeon et al, 1993; McDonald and Weiskopf, 2001), and has been demonstrated to be easy for use by patients (Melzack, 1987; Helme et al, 1989). Although it has not been directly validated for use in patients with wounds, it has been widely used in studies within the wound care realm (Cullum and Roe, 1995; Noonan and Burge, 1998; Walters et al, 1999). The SF-MPQ incorporates 14 pain descriptors assessing both sensory and affective pain dimensions scored on a 4-point scale from 0 (None) to 3 (Severe). A 100mm Visual Analogue Scale (VAS) is included to measure overall intensity. The SF-MPQ was administered before the initial application of Actiform Cool and on completion of the audit.

Patients were also asked to report on any changes in their experience of pain and to comment if the pain had any effect on their activities of daily living, such as sleep and mobility. This was to again to elicit the views of the patient's experience and any effect on outcomes that were important to them and impacted on their quality of life. Any changes to dosage and frequency of analgesia used to control wound pain were also recorded.

Actiform Cool was applied in conjunction with any previously used treatment, such as compression bandaging. They were able to increase or decrease their analgesia as required as the dressing was to be used as an adjunct to standard methods of pain control. Patients remained on the audit for up to five weeks depending on the progress of the wound, effect on pain levels and personal preference. Patients were audited using Actiform Cool for up to four weeks. The final assessment was performed on the next routine clinic appointment, unless contacted by the patient with any concerns. Interim dressing changes were performed either by the patient or community nursing team.

Results

Twenty-one patients were included in the audit who presented with wounds of varying aetiologies:

- ▶ Venous leg ulcers (n=15)
- ▶ Mixed arterial/venous leg ulcers (n=2)
- ▶ Traumatic leg ulcer (n=1)
- ▶ Vasculitic ulcer (n=1)
- ▶ Pyoderma gangrenosum (n=1)
- ▶ Rheumatoid ulcer (n=1).

Nineteen of the patients recruited suffered with complex, often multiple, co-morbidities in addition to the underlying disease associated with their wound type. These included diseases such as osteoarthritis, diabetes mellitus, ischaemic heart disease, myasthenia gravis, genetic disorders which affect the lung, liver and blood, autoimmune diseases such as rheumatoid and psoriatic arthritis and inflammatory disorders, such as ankylosing spondylitis. Three patients also suffered with depression requiring treatment with anti-depressant medication. These co-existing conditions, in addition to the wound itself, contributed to the complexity of patient management both in terms of wound healing and pain, and their effect on quality of life.

Short-Form McGill Pain Questionnaire

The results of the SF-MPQ were analysed as recommended by the original publication (Melzack, 1987), by obtaining an overall score which included the results of the VAS score in combination with a score for the number and intensity of pain descriptors recorded pre- and post-application of Actiform Cool. This takes into consideration the overall pain experience as captured by the SF-MPQ, rather than just a VAS score in isolation.

Changes in pain levels were assessed through analysis of the SF-MPQ pre- and post-use of Actiform Cool. Two of the withdrawn patients did not attend for the final post-Actiform Cool assessment and so data was not captured on the SF-MPQ — therefore, data was analysed on changes in pain levels for 19 patients only. A non-parametric Wilcoxon Signed Ranks Test was used

to determine if there was a statistically significant difference in pain scores following the use of Actiform Cool. Parametric tests were not appropriate as the data was found to be not normally distributed.

The results indicated a median overall pain score of 80 (range=93) before using Actiform Cool, which decreased to 73 (range=122) after using the dressing. The small sample number and large spread of scores, as indicated by the large ranges above, led to this difference being deemed not statistically significant ($p=0.073$).

The results of the VAS were also analysed independently using the same method, which indicated a median score of 68 (range=66) before using Actiform Cool, which decreased to a median score of 60 (range=95) post-Actiform Cool. This result was found by the Wilcoxon Signed Ranks Test to be statistically significant ($p=0.027$), although this result should be interpreted with caution again due to the small sample number and large range of scores.

In terms of pain descriptors, overall there was no overwhelming change in any particular descriptor following the use of the dressing. The most commonly reported type of pain was 'tender'; 84% (n=16) of patients reported this before using the dressing, and a small decrease in overall occurrence was noted after using the dressing (79%; n=15). The largest decrease was in the number of patients who reported experiencing hot-burning pain — 68% (n=13) had initially reported experiencing this type of pain before using Actiform Cool, compared with 47% (n=9) after. An overall decrease in the severity of shooting, gnawing, hot-burning and splitting pain as assessed on the SF-MPQ was also observed.

For individual patients, the use of Actiform Cool significantly decreased their pain scores when using the SF-MPQ, which is not necessarily reflected in the results when analysed as a whole, but will be demonstrated later in this article using individual case reports.

Pain

Twelve patients (57%) reported an overall decrease in pain levels after using Actiform Cool, with seven of these requesting to continue using the dressing on completion of the audit.

Seven patients experienced increased pain with the use of Actiform Cool — for three of these patients this was only determined through patient report, and not reflected in the results of the SF-MPQ scores. Two patients recorded unchanged pain levels, although one of these requested to continue with the dressing after audit completion.

Twelve patients completed the audit. The dressing was discontinued after less than two weeks in nine patients for a

Table 1

Duration of patient enrollment in the audit

Patient number	Duration of audit participation (days)
1	14
2	14
3	21
4	18
5	14
6	14
7	7
8	8
9	7
10	8
11	7
12	28
13	6
14	14
15	7
16	14
17	7
18	14
19	4
20	21
21	12

variety of reasons:

- ▶▶ Infection (n=3)
- ▶▶ Reported increased pain with associated wound deterioration (n=3)
- ▶▶ Increased pain on dressing application (n=1)
- ▶▶ Possible skin reaction to the dressing (n=1)
- ▶▶ Increase in wound size and odour (n=1).

The three patients who developed infection which ended their participation in the audit, and the one who requested the dressing be removed due to increased wound size and odour, were reporting decreasing pain levels before these events.

Analgesia

Four patients were able to reduce their analgesia following treatment with Actiform Cool. Fourteen patients remained on the same dosage and frequency of their analgesia even if their wound pain was improved, as the analgesia was often being used to manage pain from other conditions. One patient was able to discontinue opiate analgesics, and was able to manage on intermittent doses of paracetamol only.

Quality of life

Although a formal measuring tool of quality of life was not used, patient comments on changes to their activities of daily living indicated cases where the use of Actiform Cool led to an improvement in quality of life.

Five patients reported an improvement in their sleep patterns and three reported improvement in their mobility. One patient stated that the dressing had made a world of difference to her life, while another found that the pain went as soon as the dressing was applied, something he had not found with other dressings. Four patients commented that as the pain improved they felt more able to go out shopping or gardening, which improved their overall sense of general well-being.

Wound status

Four patients went on to achieve complete wound closure shortly after

completing the audit. Three patients also experienced a decrease in wound dimensions, and evidence of increased granulation tissue was also observed in three patients. One patient's ulcer remained unchanged in size, but the wound bed was more hydrated and edges appeared more active.

Nine patients experienced an increase in wound size, with five of these also developing maceration to the surrounding skin. The increase in size was noted in association with infection for two of these patients, but the possible cause of the increase for the remaining patients was unable to be determined with any certainty. One patient experienced no change in the status of her wound, although she only remained in the audit for one week.

Case studies

Four cases where Actiform Cool produced a successful outcome on the wound-related pain of patients with complex wounds will now be presented.

Case study I

Clinical scenario

Mr L is a 48-year-old man with a five-month history of recurrent venous ulceration to the right lateral malleolus. Mr L suffered with ankylosing spondylitis, which was treated with methotrexate, an immunosuppressant, and diclofenac to reduce inflammation and for general pain control.

Clinical presentation

Mr L presented with a static, sloughy venous leg ulcer measuring 8.5 x 2.5cm

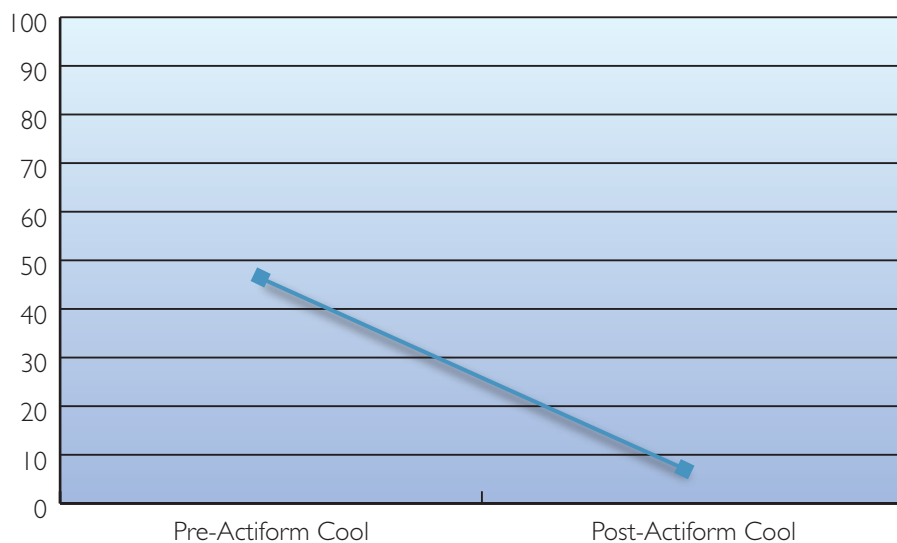


Figure 1. Changes in the VAS score pre and post-Actiform Cool in case study I.

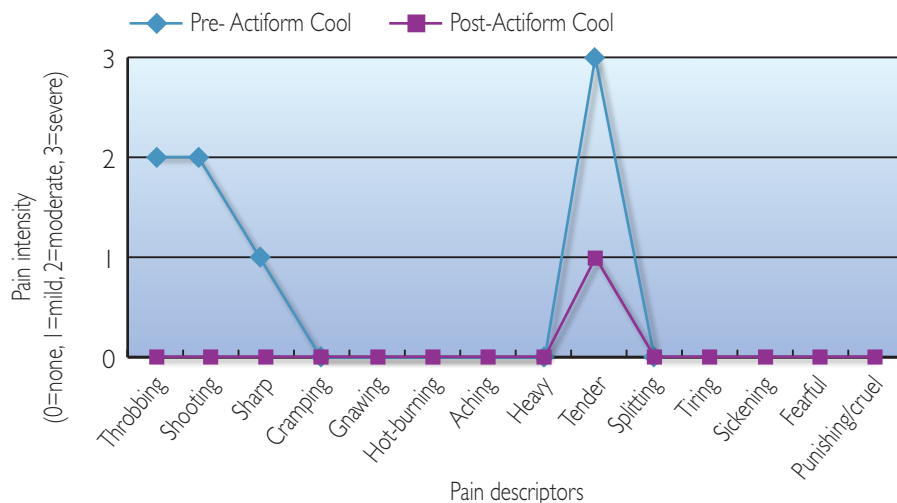


Figure 2. Change in SF-MPQ Results Pre- and Post- Actiform Cool in case study I.

with some evidence of granulation tissue. Exudate levels were minimal, with erythema, oedema, eczema and dryness to the surrounding skin.

A SF-MPQ was completed to assess his ulcer pain, and it was evident from Mr L's comments that this was severely affecting his quality of life. He described how the pain disturbed his sleep, and how his mobility was affected as he was unable to put his foot fully flat on the floor. His pain was poorly controlled with his current analgesia and he described it as 'feeling like a knife'. Mr L had been experiencing high pain levels in the ulcer since its recurrence five months previously, and in previous ulcerations over several years to the same site. He had to rely on his wife for assistance with his daily activities and with changing his dressings.

Treatment outcome

Mr L continued with his current treatment for a further week, at the end of which he stated that the pain was still affecting his mobility, describing it as 'biting, stinging and stabbing'. Actiform Cool was applied along with modified compression, with emollients and a mild steroid ointment to treat eczema to the surrounding skin.

After two weeks, Mr L's pain levels had much improved. *Figures 1 and 2* indicate the changes in pain descriptors and VAS scores recorded pre- and post-Actiform Cool. Mr L requested to continue with Actiform Cool as his primary dressing. Increased granulation tissue and more active wound edges were also observed in the ulcer itself, with a decrease in length to 8.1 cm. However, as Mr L had been commenced on modified compression at the same time as the Actiform Cool, these effects could be attributed to the combination of treatment, and not just the Actiform Cool in isolation.

Case study 2

Clinical scenario

Mrs C was a 71-year-old woman with a 10-year history of venous ulceration to the left medial malleolus. Her only medication was regular co-codamol for ulcer-related pain.

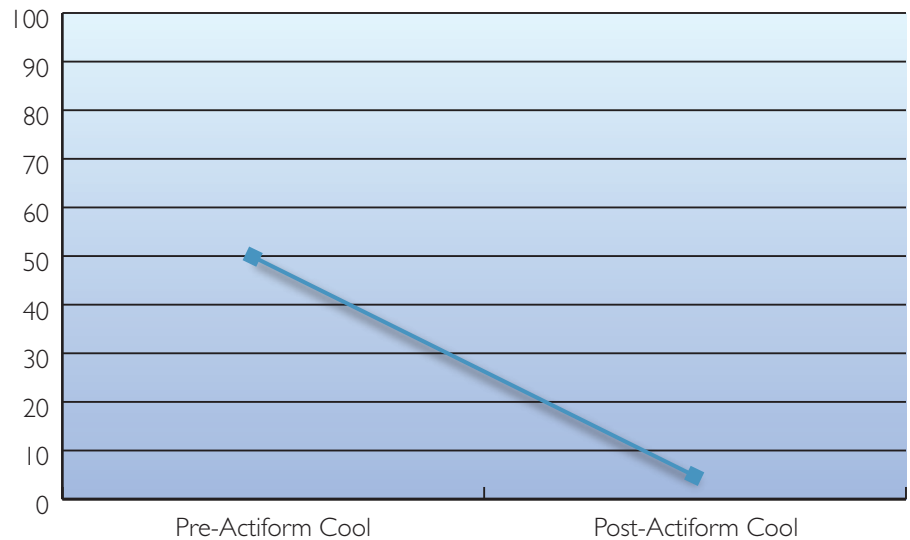
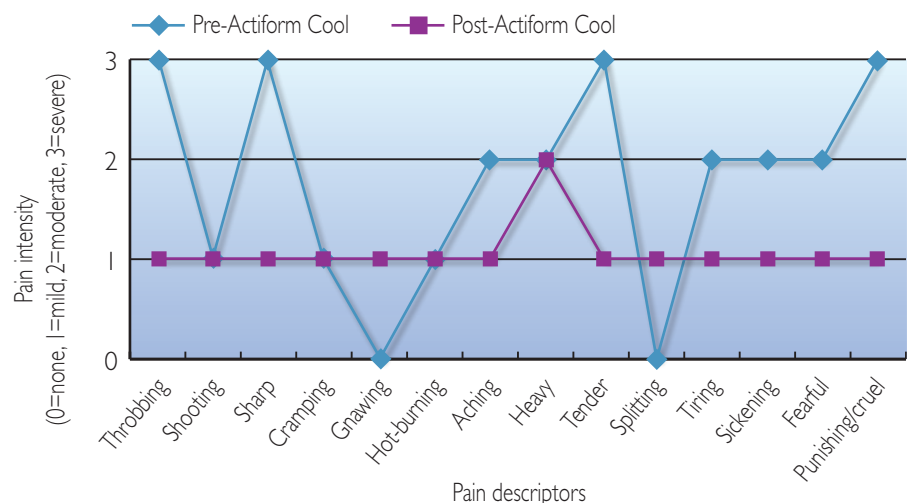


Figure 3. Changes in the VAS score pre and post-Actiform Cool in case study 2.



I did this cool again It was Pos

Figure 4. Change in SF-MPQ Results Pre- and Post-Actiform Cool in case study 2.

Clinical presentation

Mrs C presented to clinic with a painful ulcer with a sloughy wound bed, minimal granulation tissue and static wound edges. The ulcer measured 1.3 x 1.5cm with a depth of 0.1 cm. Exudate was minimal, with erythema, dryness and eczema noted on the surrounding skin.

The nature and intensity of the pain experienced by Mrs C was assessed using the SF-MPQ, and she reported that ulcer pain disrupted her sleep pattern and mobility. She was unable to go out shopping on her own, despite her analgesia. Dressing her wound and performing interventions was difficult due to the levels of pain she experienced.

Treatment outcome

Mrs C's identified problem was constant severe pain in her ulcer which adversely affected her sleep, mobility and overall general well-being. She was commenced on Actiform Cool dressings and continued with her current Class II compression hosiery.

When attending a community clinic two weeks after commencing Actiform Cool, Mrs C was experiencing less ulcer pain and only required analgesia to go to bed. She felt a lot brighter in herself, was sleeping better and stated it was the 'best week I've had in years'.

After a further two weeks, Mrs C was reviewed in the specialist

outpatient's clinic for her final assessment, by which point she was no longer requiring analgesia and was reporting no pain. Figures 3 and 4 represent the overall changes in her SF-MPQ and VAS scores before and after using the dressing. Mrs C was able to go out for walks and commented that Actiform Cool had 'made a world of difference to my life. This dressing is marvellous'. A significant decrease in wound size was observed over the course of the audit, and Mrs C requested to stay on the dressing.

Case study 3

Clinical scenario

Mrs H was a 71-year-old woman with a long-standing history of recurrent ulceration to her feet and legs related to rheumatoid arthritis. The rheumatoid arthritis was being managed with azathioprine and prednisolone tablets. Mrs H had previously had arterial bypass surgery to her right leg, and also suffered with heart disease and anaemia. Among a large amount of other medication, she took modified release morphine sulphate tablets and paracetamol for general pain relief.

Clinical presentation

Mrs H presented to the outpatients' clinic with multiple ulcerations to her right and left medial malleoli, the gaiter region of her right leg and a large ulcer to the dorsum of her left foot, which was noted to be particularly painful. This area measured 7.2 x 4.0cm with a depth of 0.3cm. The ulcer beds were sloughy and granulating, with static wound edges. Surrounding skin was erythematous, oedematous and dry and flaky, with minimal to moderate levels of exudate. Mrs H had a complex history and had experienced pain for many years.

She was able to distinguish her ulcer pain from the pain caused by her other disease. Mrs H completed a SF-MPQ which recorded severe pain for many descriptors, and she also added stinging as another descriptor. The pain was affecting her sleep and mobility and she was unable to wear footwear comfortably.

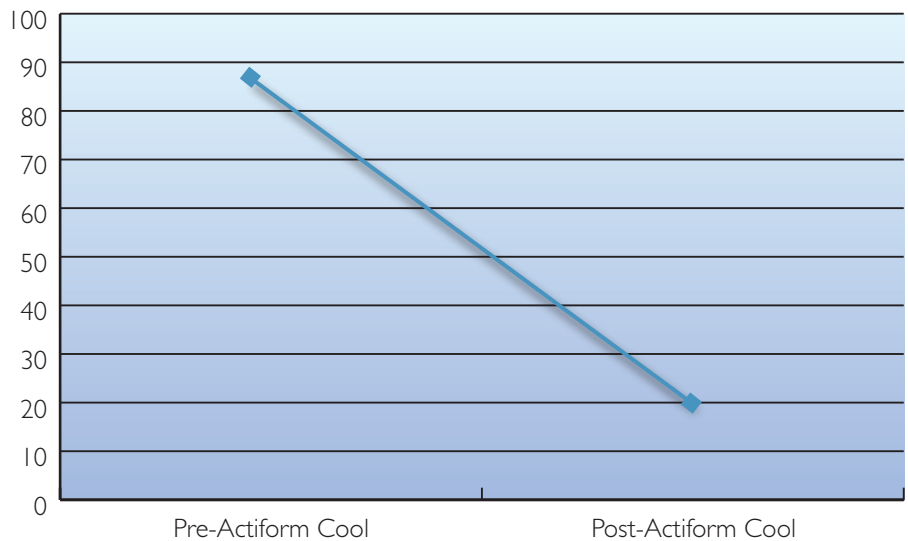


Figure 5. Change in VAS Score Pre- and Post- Actiform Cool in case study 3.

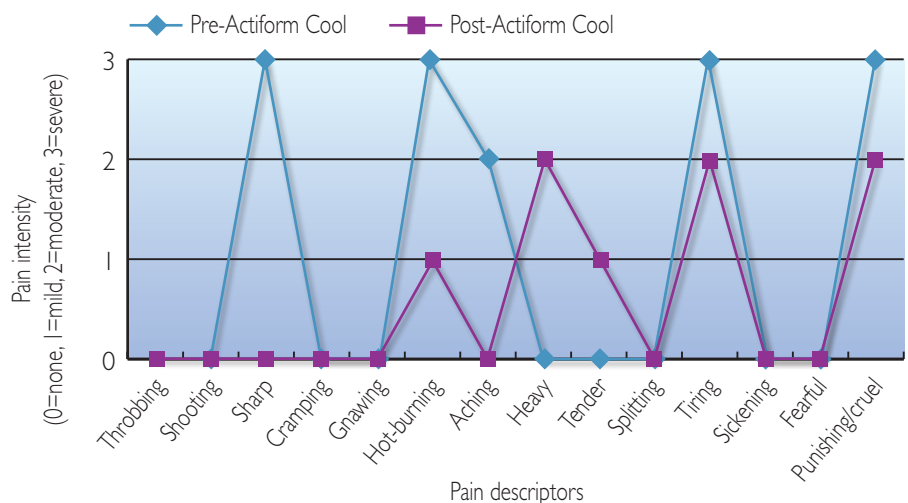


Figure 6. Change in SF-MPQ Results Pre- and Post- Actiform Cool in case study 3.

Treatment outcome

Pain in the ulcer on the dorsum of her foot was identified as the main problem so it was decided to apply Actiform Cool with the aim of reducing her ulcer pain. Due to Mrs H's complex history and co-morbidities, she regularly attended clinic and so was monitored more frequently than other audit participants.

Following one week of treatment with Actiform Cool, Mrs H reported that she felt the dressing had helped with her ulcer pain. She expressed the pain as 'sore'. The dressing was being cut to the size of the wound to prevent maceration to the surrounding skin.

One week later, Mrs H felt the ulcer pain was much improved again, and stated her mobility was slightly improved. Her sleep remained disturbed, although she felt this was not wholly related to her ulcer pain but also related to her rheumatoid arthritis generally.

Mrs H stated on the final assessment visit that although she continued to experience pain, overall the dressing had definitely helped, which is highlighted in Figures 5 and 6. The pain was also better in the left leg where all the ulcers were being treated with Actiform Cool, compared to the right leg which had continued with non-adherent dressings. Of particular interest is that Mrs H reported that she was no longer taking her morphine tablets since using

Actiform Cool, and was now managing on paracetamol taken intermittently, which is a significant decrease in type and frequency of analgesia.

The dimensions of the ulcer to the dorsum of the left foot remained the same, although the ulcer appeared slightly shallower and there was healthy granulation tissue evident at the base.

Overall, the Actiform Cool dressings had a very positive effect on Mrs H's pain experience, which was highlighted both by her comments, the outcomes of the SF-MPQ pain assessments and the discontinuation of morphine analgesia. Mrs H requested to continue with the dressings on completion of the audit.

Case study 4

Clinical scenario

Mr J is a 55-year-old male with a three-year history of venous ulceration. Due to the pain in his ulcer he took regular ibuprofen, in addition to a beta-blocker to treat hypertension.

Clinical presentation

Mr J presented with a venous leg ulcer over the left medial malleolus. The ulcer had developed initially from a traumatic injury. On initial wound assessment, the wound bed was granulating with evidence of slough. The wound edge was epithelialising with signs of erythema, oedema and haemosiderin staining to the surrounding skin. Wound exudate levels were minimal.

An initial pain assessment using the SF-MPQ was performed, which indicated the wound pain was of moderate severity but was tolerable with his analgesia. The pain from the ulcer did not affect his sleep pattern or his activities of daily living. Mr J had to work full-time despite being in pain from his ulcer.

Treatment outcome

After two weeks of using Actiform Cool as a primary dressing, assessments captured an improvement in pain levels. Mr J commented that he had reduced his analgesia and was now taking only one ibuprofen in the morning. When using the SF-MPQ to describe the ulcer-related pain, the severity was now

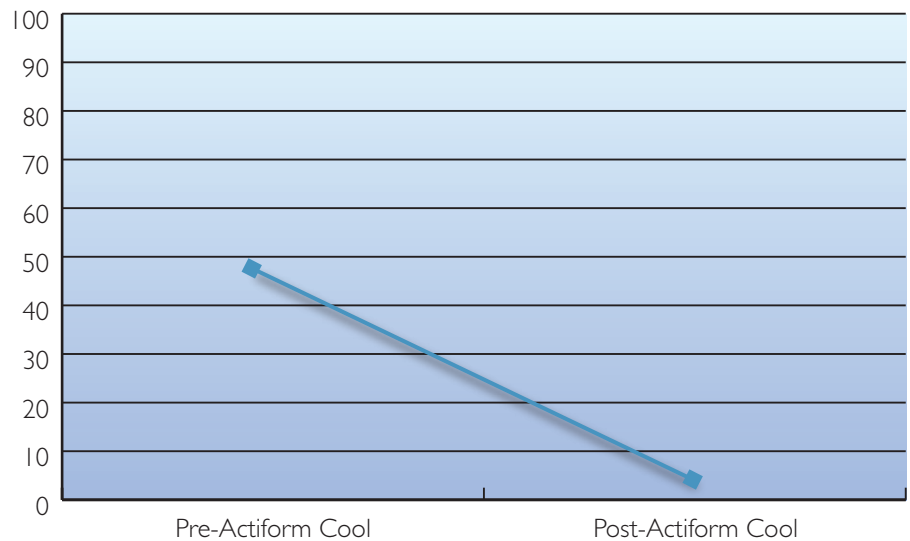


Figure 7. Change in VAS Score Pre- and Post- Actiform Cool in case study 4.

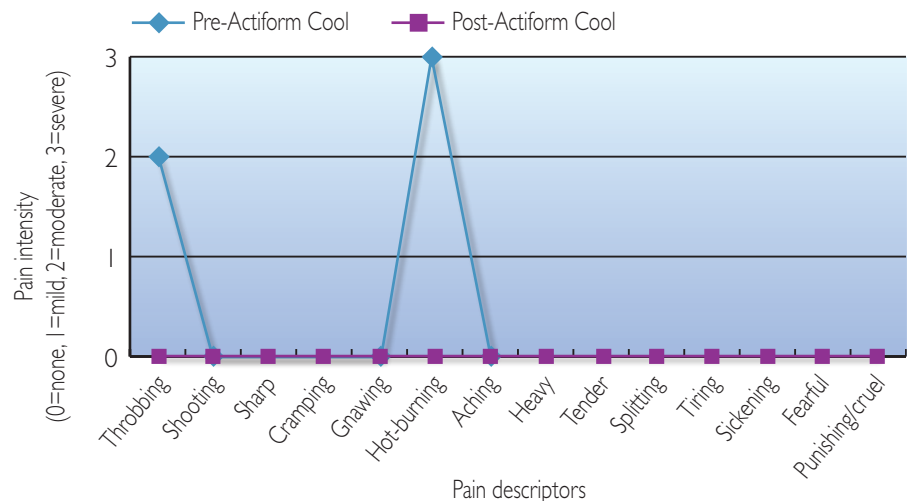


Figure 8. Change in SF-MPQ Results Pre- and Post-Actiform Cool in case study 4.

reduced to mild. Figures 7 and 8 indicate the reduction in pain levels recorded during the audit period. The ulcer almost healed during the audit period, and went on to completely heal within a few weeks of completion.

Discussion

The overall outcome of the audit reinforces the belief that Actiform Cool has the potential to reduce pain in some patients when used as part of an overall pain management treatment plan. Although the dressing was not successful in every case and the results of the changes in pain levels from the SF-MPQ were not statistically significant, it was still considered a successful outcome by those patients whose pain decreased. Although a

validated pain assessment tool was used, on occasions the results of this were not always consistent with the patient's self-reports, which makes the results of an audit such as this difficult to fully interpret based on statistical evidence alone. Consideration needs to be given to the fact that many of these patients have both complex wound and general medical problems that can influence outcomes and make them difficult to predict. It should also be acknowledged that other treatments such as compression, which were utilised alongside Actiform Cool, and the short period of time over which the dressing was assessed, make it difficult to conclude that the use of Actiform Cool was the only factor contributing to pain reduction.

The issues above may also contribute to the conclusion that it cannot be determined with any certainty at present when Actiform Cool will provide effective pain relief. For several patients included in the audit with very painful wounds, multiple complex comorbidities and who were on various types of analgesia, the application of Actiform Cool was of benefit for some and not others. The important point that should be acknowledged from the results of this audit is that in the real world of clinical practice, Actiform Cool can improve the experience of pain in patients with a variety of complex wounds, an outcome which may not have been determined by the study of straightforward patients enrolled in an RCT.

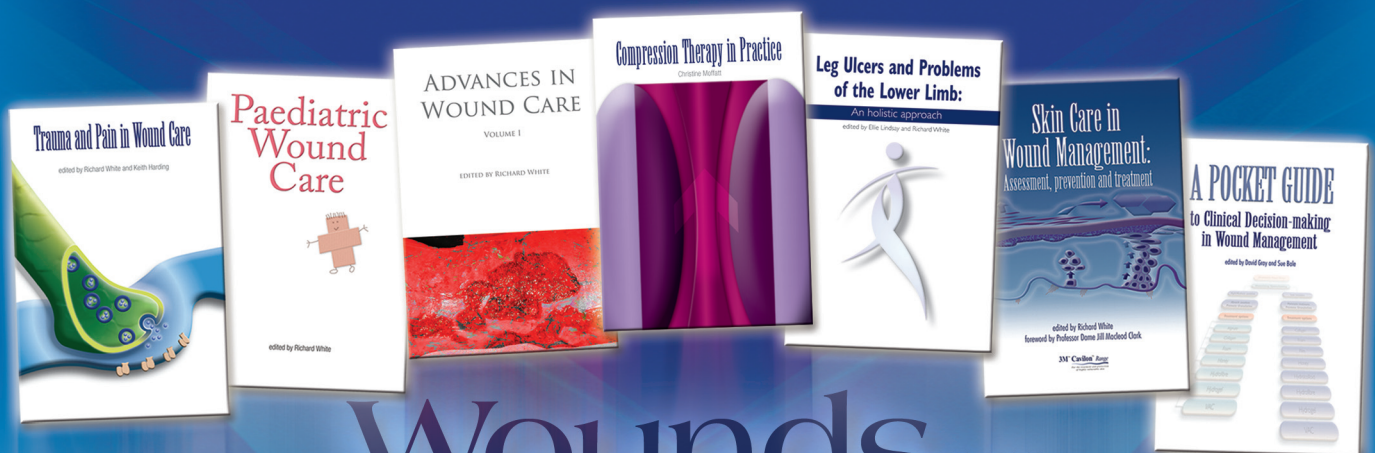
The resulting decrease in frequency or dosage of analgesia for four patients was also an important outcome considering the reluctance of some patients to take sufficient amounts of oral analgesia to control pain, and due to the side-effects that may be

experienced. The patient that was able to discontinue opiate analgesia was especially significant considering the side-effects of this type of medication and with consideration to the fact that she suffered with severe rheumatoid arthritis. Although she still experienced some discomfort from this, her wound pain was markedly improved and she was managing to control her pain with intermittent paracetamol only.

The issue of wound pain and the use of dressings which have the potential to reduce pain is definitely an area which merits further investigation. As Hollinworth (2005) stated it may not be feasible to completely eliminate wound-related pain in every patient, but it is usually possible to modify the patient experiences. The use of Actiform Cool dressings may be one such method of achieving this. The management of a patient's pain may have the ability to impact on healing rates through areas such as improved sleep, decrease in physiological stress responses and in the ability to tolerate higher levels

Key Points

- ▶ Determining the success of interventions on measures such as pain and quality of life is difficult with traditional outcomes using physiologic endpoints.
- ▶ Measuring outcomes using conventional research methods is problematic for complex patients.
- ▶ Actiform Cool has the potential to reduce wound pain for some complex patients.
- ▶ Further research into topical treatments of painful wounds is required.



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of compression, as well as leading to improved quality of life.

It can be seen from the case studies presented that it is not always possible to predict outcomes with complex patients. The audit results illustrate the impact that a simple hydrogel dressing can have on severe pain from complex ulceration. According to traditional evidence hierarchies, this would not be considered strong evidence on which to change practice, yet it provokes the thought that sometimes consideration needs to be given to simple treatments that have been shown to be effective in certain cases.

Healing is often considered to be a primary measure of success within wound care, yet with an audit such as this where healing was not a primary endpoint, both the patient and clinicians felt that a successful outcome had been achieved as pain levels had decreased, mobility or sleeping patterns had improved and an overall increase in quality of life was reported.

Conclusion

Wound pain is often one of the symptoms patients find particularly distressing (Charles, 1995; Ebbeskog and Ekman, 2001), and studies suggest the prevalence of pain in patients with pure or mixed venous ulcers is approximately 50% (Hofman et al, 1997; Nemeth et al, 2003). For 12 patients in this audit, the use of Actiform Cool had a significant impact on their pain and its effect on their daily lives. This is an important outcome to consider for clinical practice as this may provide another 'weapon in the armoury' when it comes to addressing the issue of wound pain without reaching for the prescription pad. This is an increasingly important consideration in terms of providing cost-effective treatment in today's economically challenged NHS, in addition to trying to limit the side-effects that can be experienced by patients with certain analgesics.

The knowledge and information available to clinicians at any one time is constantly evolving due to an ongoing research process. The consequence

of reconsidering traditional outcome measures in wound care is that a broader view of what constitutes success needs to be observed. Consensus on complex wound management is difficult to achieve, especially considering the multiple factors that may affect individual patients. The case reports and overall audit results indicate that statistical differences cannot be assumed as an absolute requirement for changing clinical practice, as they do not necessarily imply clinical significances — flexibility and an acknowledgement of the reality of clinical practice needs to be acknowledged when considering the importance of outcome measures and traditional views regarding hierarchies of evidence. **WUK**

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